Attachment 3: Statement of Work

STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall provide support to the Cancer Therapy Evaluation Program (CTEP) Regulatory Affairs Branch (RAB) and Investigational Drug Branch (IDB) for a wide range of services as described below. The Contractor will also provide similar support for the Cancer Imaging Program, Division of Cancer Treatment and Diagnosis (DCTD) under this Contract and any other NCI offices as designated by the Contracting Officer's Representative. The Contractor shall furnish services, qualified personnel, material, equipment, including secure computers, high speed-high capacity data link to NCI servers, computer support, and facilities not otherwise provided by the Government under the terms of this contract, including maintenance of appropriate software and licenses as needed to perform the clinical research support tasks set forth below. All of the aspects of this in-depth tracking of investigational agent information shall require frequent face-to-face, one-on-one meetings to discuss strategies and tasks and to review and analyze data.

1. Provide support for the preparation, tracking, submission and distribution of CTEP drug development related documents and FDA submissions.

Support for drug development related documents and FDA submissions include but is not limited to: investigational agent development plans, clinical research information management and writing, protocol templates, organizing, publishing, and submitting Investigational New Drug Applications (INDs), Master Files (MFs), Center for Devices and Radiological Health (CDRH) Pre-Submissions, Pre-IND/EOPh2 Briefing Packets, FDA Annual Reports, Investigational Drug Exemptions and Investigator Brochures. There are currently approximately120 active INDs within the CTEP, DCTD portfolio with approximately 600 clinical studies.

A. Assist in the preparation, submission and tracking of approximately 20-35 Investigational New Drug Applications (INDs) as well as Pre-IND/End of Phase 2 (EOPh2) Briefing Packets and IND related correspondence per year. Assist in the withdrawal of INDs from the FDA after CTEP clinical development is discontinued.

i. Access scientific literature databases (e.g. PubMed, ASCO abstracts and others) and CTEP shared network drives to retrieve scientific data for inclusion in the IND. The contractor shall perform literature searches for each new IND drafted and each IND annual report and obtain relevant literature references for the agent the IND is being prepared for and prepare INDs in a Common Technical Document (CTD)/electronic Common Technical Document (eCTD) format with appropriate PDF bookmarks suitable for both paper and electronic FDA submissions. InSight® software shall be used to assemble, publish and submit electronic INDs. Rosetta Phoenix™ shall be

used to view eCTD documents. The format and content of the IND shall be in accordance with FDA (21 CFR 312) and NCI requirements.

ii. Edit, index and format the data (e.g. pharmacology/toxicology, chemistry manufacturing and controls, previous human experience) obtained for the IND and distribute in conformance with the requirements of RAB and the FDA.

iii. For paper INDs, prepare original and additional copies of the IND (at least 4) to be delivered to the FDA and stored at the Contractor site. Additional copies may be requested by the COR and the Contractor will be directed on where to send them. Electronic files of the IND should be entered in the Regulatory Affairs Branch Information Tracking System (RABITS) database and saved in RAB designated shared drives.

iv. For electronic INDs, prepare a FDA electronic gateway compatible electronic Common Technical Document (eCTD) IND document.

v. Draft and distribute internal and external communication regarding FDA correspondence and IND status. Prepare memoranda (historically 30 to 45 per year) for IND activations, inactivations, transfers, and withdrawals. All such memos should be distributed to NCI staff and filed with the appropriate IND file and also be available as an electronic copy.

vi. Draft and update existing tables (historically 30 to 45 per year) of agent specific adverse events, i.e. Comprehensive Adverse Event and Potential Risks (CAEPR) and Specific Protocol Exceptions to Expedited Reporting (SPEER) as needed according to Adverse Event (AE) incidence and severity for each investigational IND agent.

vii. Prepare Condensed Risk Lists in lay language for each investigational agent (historically 20 to 35 per year) for use in informed consent documents.

viii. Abstract protocol-specific exceptions from each new protocol (35 to 60 per year) and enter into the electronic safety reporting modules, CTEP-Adverse Event Reporting System (CTEP-AERS). Amendments (historically 650 to 850 per year) will be assessed for changes to protocol-specific exceptions entered into electronic safety reporting modules accordingly. Access to CTEP-AERS is a web-based password protected application.

ix. Prepare and submit Pre-IND/End of Phase 2 (EOPh2) briefing packets (historically 5 to15 per year) to the FDA when requested by NCI. NCI will determine if these submissions will be in paper or electronic format.

x. Draft Cross Reference Authorization Letters (historically 30 to 40 per year) and file them in appropriate databases. Enter internal and external Cross Reference Authorization Letters into the database and electronic file.

xi. Prepare letters (historically 60 to 80 per year) to investigators for comments arising from FDA review of INDs and protocols. Prepare letters (historically 60-80 per year) to the FDA from responses received from investigators. The dates that letters are sent and that responses are received shall be tracked in RABITS and follow-up letters to investigators must be sent requesting responses if responses are not received within 45 calendar days or other specified timeline of the initial request.

xii. Deliver IND specific materials and files (historically 900 to 1100 items delivered per year) to the FDA, the NIH Facilities and other local sites including the Office of Biotechnology Activities (OBA) by courier services with document tracking. Provide courier service between CTEP offices and the Contractor site when requested on any federal business day.

xiii. Prepare written reviews (historically 150 to 200 per year) for the Protocol Review Committee, CTEP, including weekly review of various sections of New Protocols (e.g., Title Page for IND/IDE status, AE reporting sections, and NCI Standard Protocol Language section).

xiv. Assess the potential for IND withdrawal of each CTEP IND during the preparation of the annual report based on the status (open and complete) of trials. Prepare a list of potential INDs to be withdrawn from the FDA and distribute this list to RAB and IDB on a monthly basis.

B. Assist, as needed, in the preparation and submission (projected range 2 to 4 per year) of Investigational Device Exemptions (IDEs) or Pre-subs with the Center for Radiological Health (CDRH), FDA. These must be in compliance with 21 CFR 812.36 (see http://www.fda.gov/cdrh/devadvice/ide/index.shtml). These submissions will be in either paper or electronic formats.

C. Maintain IND files and databases

i. Assemble, organize and prepare amendments (historically 900 to 1100 per year) to INDs as required by FDA requirements (21 CFR 312) and NCI policy (in either paper or electronic format). This task includes protocols, protocol amendments, AE reports, Annual Reports, additional chemistry and manufacturing information, toxicology information, investigator brochures, FDA correspondence and special exceptions. This includes preparation of the 1571 Form, 3674 Form, and cover letter.

ii. Distribute IND amendments (historically 900 to1100 per year) (3 paper or 1 electronic) to the FDA Office/Division responsible for the particular IND. In those instances where there is a pharmaceutical collaborator, a copy of the amendment shall be forwarded electronically to the pertinent pharmaceutical collaborator. Copies submitted to the FDA shall be submitted in accordance

with FDA policies and regulations.

iii. Maintain orderly electronic files of all CTEP related documents including INDs, Annual Reports, amendments, cross reference authorization letters and collaborator documents on a shared network folder and in a back-up folder and RABITS (when applicable). Authorized NCI and Contractor staff has access to the shared network folder. NCI will determine which staff will be granted access. The database shall include both serial number submissions as well as supporting documentation. The contractor shall ensure the security of the files such that there is no unauthorized access or disclosure and shall ensure protection from fire.

iv. Maintain accurate indexes (e.g. RABITS, IPAD, Access) of IND applications and IND submissions (Definitions of indexes found on page 17-19 of SOW).

v. Maintain accurate RABITS and IPAD databases for tracking (status of anticipated/pending INDs, appropriate distribution of IND amendments to third parties, FDA communications), Cooperative Research and Development Agreements (CRADAs) (historically 50 to 65 active per year) and Clinical Trials Agreements (CTAs) (historically 35 to 50 active per year) as well as IND status. The databases are developed and maintained under a separate NCI contract.

vi. Maintain several existing databases which assist the DCTD in meeting federal regulations mandated for IND sponsors (e.g. CTEP-AERS, RABITS, electronic safety reporting modules, Drug Disease Matrix, collaborative agreement Database).

vii. Maintain up-to-date project plans (historically 50 to 70 per year) and accurate databases relating to various aspects of investigational agent development.

D. Update NCI Master Files (MFs) (historically 2 to 4 per year) from data provided by the RAB (e.g., clinical protocols, preclinical, toxicology, chemistry and manufacturing information).

i. Access scientific databases to retrieve scientific data for possible inclusion in the MF.

ii. Edit, index, and format data in conformance with the requirements of the RAB/FDA. Format the Master Files in either paper or electronic format as directed by NCI.

iii. Prepare internal memoranda noting the MF submissions and withdrawals.

E. Monitor and maintain collaborative research agreement related records and forward appropriate documents to collaborators.

i. Attend selected meetings (historically 20 to 30 per year) between NCI and pharmaceutical collaborators to assist in the scientific, regulatory and technical tasks in this Statement of Work.

ii. Prepare meeting minutes from meetings or conference calls between NCI and pharmaceutical collaborators on an *ad hoc* basis.

iii. Generate letters, maintain mailing lists, and perform queries of the relevant database as needed and other related tasks as assigned.

iv. Prepare, update and distribute an accurate Pharmaceutical Collaborator Contacts list quarterly listing all of the collaborators that interact with CTEP. Contractor will be sent updated information from CTEP staff, collaborators directly or the Protocol and Information Office. All updates must be included in the next report with a listing of the changes made to the report.

v. Prepare the monthly anticipated IND list and IND potential withdrawal list for e-mail distribution to DCTD staff in RAB, Investigational Drug Branch (IDB), Pharmaceutical Management Branch (PMB), Protocol Information Office (PIO), Project Management Office (PMO) and the Developmental Therapeutics Program in advance of the monthly meeting. (For organizational information refer to the DCTD website: http://dctd.cancer.gov/).

vi. Perform protocol reviews pertaining to Agreements (i.e. CRADA, Clinical Trial Agreement, etc.) language (historically 5 to 10 new protocols per week).

vii. Distribute copies of IND documents (historically 900 to1100 per year) to appropriate collaborator(s) according to timelines determined by NCI.

viii. Maintain an accurate and updated database of pharmaceutical collaborator contacts (historically 120 to 150) noting which communications are forwarded to specific collaborators.

ix. For protocols with more than one investigational agent, assure that only documents pertaining to the pharmaceutical collaborator's agent are provided to designated company contacts.

F. Prepare, for IDB staff on a quarterly basis, or in some cases on an *ad hoc* basis, summary tables and reports (historically 250 to 275) from information in CTEP informatics databases updating clinical trial status, accrual, response results and adverse events.

Additional *ad hoc* reports include:

i. Agent Development Plan Reports
The Contractor shall prepare agent specific meeting reports (historically 50 to 75 per year) using data in the CTEP enterprise system from templates prepared by NCI. These will be requested on an *ad hoc* basis to coincide with company meetings.

ii. Aggregate Safety Reports
The Contractor shall prepare safety profile reports and spreadsheets across protocols and/or investigational agents.

iii. Comprehensive Reports
The Contractor shall prepare a comprehensive review and summary of data within an IND or across INDs.

iv. Clinical Study Reports (CSR)
The content and format of the CSR shall meet the guidance issued by the International Conference on Harmonization (ICH) E3:
Guideline for Industry Structure and Content of Clinical Study Reports and the Investigational Drug Branch.

G. Prepare and edit IND Annual Reports for each active IND for submission to FDA in accordance with FDA requirements (21 CFR.312.33). These reports may be prepared in part with tables and merged data from the CTEP enterprise informatics system. FDA Annual Report preparation will require extensive literature searches, writing, fact checking as well as tracking AE reports. If requested, assist in the transition to the Development Safety Update Report (DSUR) and prepare DSURs for each agent according to FDA and/or ICH guidance.

H. Prepare, as needed, Investigator's Brochures (approximately 5) from information provided by NCI. Investigator Brochures shall be prepared in accordance with FDA requirements (21 CFR 312.23(5)). Update the Investigator's Brochures annually or as directly by RAB or IDB while the agent is in clinical development.

I. Attend scientific meetings (historically one support staff for each 50 to 75 meetings), and/or meet periodically with Clinical Investigators and Data Managers involved in the conduct of NCI-sponsored clinical trials to record meeting minutes and organize and discuss scientific study results and data retrieval.

J. Draft preliminary development plans (historically 10 to 20 per year), Project Team Application (PTA) Announcements and written responses for Investigational Drug Branch (IDB) physicians to investigators who have submitted protocols or Letters of Intent (LOIs) (historically 200 to 250 per year). These letters shall reflect the discussion of the Protocol Review Committee regarding the protocols and LOIs. Written responses shall be sent to the

investigator and the pharmaceutical collaborator, if applicable.

K. Prepare and update generic templates (historically 5 to 10 per year) for protocols, as well as specific templates for, e.g., organ dysfunction studies and agent-specific templates as needed.

L. Support NCI activities at the Biomarker Review Committee (BRC) by abstracting biomarker information from submissions to NCI and maintaining an accurate database of utilized biomarkers. Track the decisions of the BRC. Distribute database data to appropriate NCI staff, Cancer Diagnosis Program staff, the Protocol Information Office and others as specified. The BRC meets once a week at most and reviews up to 5 proposals per meeting historically.

M. Support PTA/LOI reviews by preparing tables (historically 15-25 tables per year) of PTA/LOIs received for review at weekly IDB meetings.

N. Support the withdrawal of INDs and other FDA applications with the FDA.

2. Monitor and Support Adverse Event Reporting.

A. Provide telephone answering service and helpdesk for the CTEP adverse event reporting telephone line (Adverse Event MD) Monday through Friday from 8:30 am to 5 pm ET except holidays. Address AE helpdesk inquiries through the AEMD E-mail address. The technical contract staff providing this support must be trained in NCI Adverse Event reporting guidelines and the use of CTEP-AERS. Historically the helpdesk has been staffed by the professional staff from the pharmacovigilance team.

B. Receive, prioritize and direct all incoming queries from clinical investigators regarding AE reporting from electronic safety reporting modules to appropriate NCI or Contractor staff during business hours. The technical contract staff providing this support will be well versed in NCI Adverse Event reporting guidelines and the use of CTEP-AERS as described above.

C. Receive, analyze, organize, and prepare an initial assessment of all expedited AE reports (historically 2000 to 2500 per year) from information received via electronic safety reporting modules in accordance with IDB Senior Investigator instructions and FDA requirements. Perform an initial assessment of the AE, obtain follow-up information as needed and prepare a written summary report when required which will be submitted to the IDB drug monitor for review. Prepare and submit the finalized IND Safety Reports to the FDA after RAB review and to pharmaceutical collaborators as directed by the COR. The existing AE database includes both reports for investigational and commercial agents; the routing of AE evaluation forms is done through a customized SharePoint® file sharing site.

D. Enter and maintain accurate adverse event data in databases. These databases include IND amendment tracking, FDA communications tracking, adverse event lists (i.e., CAEPRs, IND database listing the status of current, withdrawn and proposed IND applications and RABITS which are part of the CTEP enterprise system).

E. Set up an E-mail mailbox to receive adverse event reports from pharmaceutical collaborators; review and forward to the assigned IDB drug monitor.

F. Provide written review of the adverse event reporting section of clinical protocols submitted to the Protocol Review Committee, CTEP.

G. Prepare cover memos for transmission of IND Safety Reports to NCI investigators.

H. Review new protocols and amendments (historically 800 to1000 per year) for protocol-specific exceptions (PSE) to expedited AE reporting, and enter the PSEs in an electronic safety reporting module.

3. Track information regarding investigational anti-cancer agents.

A. Maintain the Integrated Platform for Agents and Diseases (IPAD) data in the enterprise data base regarding agent characteristics, preclinical pharmacology data, and agent priority, significant results, reasons for agent interest, target interaction, clinical development stage, agent supply and contact information. Enter information into IPAD regarding pivotal non-NCI studies performed by pharmaceutical collaborators.

B. Maintain project plans for each investigational agent in development (historically 60 to 80 per year). Project plans shall include summary information on each stage of drug development (preclinical studies, anti-tumor activity, toxicity, mechanism of action, Phase 0, Phase 1 trials with status, toxicities, Phase 2 trials with response rates, status, etc.).

C. Maintain an accurate and up-to-date Drug-Disease Matrix which tracks investigational agents available for study in standard diseases on an annual basis or more frequently as requested by NCI.

D. Survey, retrieve and assemble clinical and supportive data on each IND agent. Technical staff well versed in NCI Adverse Event reporting guidelines shall conduct in-depth investigational agent information and data analyses (e.g., analysis of agent effects, adverse events and pharmacokinetics by dose level).

E. Conduct literature searches (historically 120 to 175 searches per year by clinical research associate or equivalently trained staff), establish and maintain

comprehensive reference databases of articles pertinent to the investigational agent, monitor published literature relevant to investigational agents, quarterly, annually or more often as required. The Contractor shall conduct literature searches and obtain one electronic copy of each relevant scientific article or abstract as requested by Program Staff within the time frames specified by Program Staff. If electronic copies are not available, a hard copy should be obtained and scanned into a PDF file. The Contractor shall maintain a permanent file of the relevant articles for each active IND application.

Maintain an investigational combination drug database for clinical trials (historically 200 to 250 trials per year) conducted by NCI. This includes knowing which protocol amendments, AE reports and other documents should be shared with which collaborators for a given combination trial.

4. Provide general technical and administrative support for investigational agent development and regulatory activities.

A. Distribute information to investigators that is relevant to investigational agent development (e.g. AE reports, updated CAEPRs).

B. On an *ad hoc* basis, perform text editing, graphics design and text editing for presentation slides (historically 20 to 30 presentations per year) or manuscripts/abstracts (historically 25 to 50 per year) in a program compatible with those in use by NCI.

C. The contractor shall be responsible for obtaining and maintaining appropriate site licenses for staff at the Contractor's site for software applications listed below which are compatible with NCI software including word processing, reference management, slides, presentations, posters and spreadsheets, etc. to allow seamless flow of information between NCI and contractor. The current software utilized by NCI for presentations, word processing, and spreadsheets is Microsoft Office 2010, SharePoint, and Adobe Pro X. The reference management software must be compatible with the software used by NCI and is currently EndNote X6. Verify that Internet Explorer and Adobe versions are compatible with all functions of InSight and electronic submissions.

D. Organize and maintain supplemental investigational agent information files (historically 110 to135 files) by investigational agent. Organize, file and maintain agent and/or pharmaceutical collaborator specific files located at NCI. Requests from NCI for information contained in these files shall be delivered within 1 hour of the request when required.

E. Maintain, store, and provide to NCI, Investigator's Brochures, Annual Reports, active and inactive IND applications, including all amendments to the IND applications, and other archived material. These materials must be readily retrievable and delivered to NCI staff within twenty-four hours from the time of a

request.

F. Store electronic copies of IND Annual Reports prepared in mandated electronic formats (Read-only Word or PDF) and provide electronic delivery of these reports within 1 hour upon request.

G. Participate in the development of live or computer based training modules (historically 3 to 5 per year) for NCI database applications and e-submissions training. Training modules shall be made available to appropriate internal and external audiences as directed by NCI.

H. Assist in the knowledge acquisition phase for the on-going development of databases/information technology aides (historically 3 to 5 per year) and beta-testing of new versions of current databases utilized by NCI.

I. Assist NCI in the preparation for audits from regulatory agencies. Historically one to two per year.

5. Maintain a Quality Control Program.

A. The contractor will have written procedures in place to allow effective continuation of work in the event of change in personnel or absence of personnel for any reason.

B. The contractor will establish and maintain updated Standard Operating Procedures for performing the tasks outlined in this SOW. The offeror will utilize those procedures as part of a comprehensive plan to demonstrate compliance with FDA regulations and NCI requirements.

C. The contractor will establish a written plan for assessment of data and document accuracy which will include procedures for:

i. Verification of accuracy of data entry and electronic files in both Contractor and NCI databases;

ii. Ensuring the accuracy of all information in Investigators Brochures, Annual Reports, letters and INDs.

iii. Ensuring accurate documents that are complete and free of grammatical and typographical errors with correct formatting.

iv. Provide secure computer systems and email for accessing and forwarding confidential and proprietary information to industry collaborators as well as secure site to access the government databases.

6. Assist in Contractor Transition.

A 3 month Phase-in transition shall apply only wherein the current Contractor is not the recipient of this award. The Phase-in coincides with the start of the contract period and is not a separate Option. A 3 month Phase-out shall apply only wherein the awardee of this contract is not the recipient of the successor award. The awardee of this contract shall assist in the transition from a predecessor Contractor (Phase-in), and of this contract to a successor Contractor (Phase-out), when applicable. A Phase-out transition period shall consist of an option period of an additional 3 months after the end of the contract period.

A. The Contractor awardee shall prepare and submit a Phase-in plan to the COR and the Contracting Officer within 15 calendar days of the award of the contract. Upon review and approval by the Contracting Officer and COR of the Contractor's Phase-In plan, the Contractor shall meet with the predecessor Contractor for briefings on execution of the Phase-in plan. The successor Contractor shall work with the predecessor Contractor to ensure that work operations are fully understood and continuity of operations are maintained through the transition.

B. In accordance with the delivery schedule, the Contractor shall prepare and submit a Phase-out plan to the Contracting Officer's Representative and the Contracting Officer 90 days prior to contract expiration date. The contractor will conduct detailed briefings regarding the policies and procedures for managing all aspects of the project with the successor Contractor. As part of these detailed briefings, the Contractor shall provide the successor Contractor with the Standard Operating Procedures Manual for Investigational Agent Development Support required by Section 5.B., above. The manual provided shall be complete, with all procedures detailed and current as of the date of the initial briefings.

C. During the Phase-out, the Contractor shall provide instruction to the successor Contractor in the policies and procedures utilized in the performance of the contract. This instruction shall be accomplished by permitting personnel of the successor Contractor to work with current contract personnel in an apprentice capacity.

D. In the Phase-out plan, the Contractor shall include a plan for the transfer of all materials and data stored by the Contractor to the successor Contractor. This plan shall include a quality assurance element which provides for determination that all electronic and hard copy files and data have been completely and accurately transferred to the successor Contractor.

E. The Contractor will be responsible for the continuity of services, adequacy and accuracy of support during the Phase-Out Option period.

Definitions and Acronyms

AE	Adverse Event	
caAERS	Cancer Adverse Event Reporting System	https://wiki.nci.nih.gov/display/caAERS/caAERS
CAEPR	Comprehensive Adverse Event and Potential Risks List	http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf#search=%22speer%22
CDA	Confidential Disclosure Agreement	http://ttc.nci.nih.gov/forms/
CDRH	Center for Devices and Radiological Health	http://www.fda.gov/cdrh/
CDUS	Clinical Data Update System electronic database For reporting clinical study results	http://ctep.cancer.gov/reporting/cdus.html
CRADA	Cooperative Research and Development Agreement	http://ttc.nci.nih.gov/forms/
CTA	Clinical Trial Agreement	http://ttc.nci.nih.gov/forms/
CTCAE	Common Terminology Criteria for Adverse Events	http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/ctcae_4_with_lay_terms.pdf
CTD	Common Technical Document	http://www.fda.gov/

CTEP	Cancer Therapy Evaluation Program - Program office within DCTD	http://ctep.info.nih.gov/
CTEP-AERS	CTEP Adverse Event Reporting System	http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTEP-AERS_Presentation.pdf http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTEP-AERS_Training_Guide.pdf
CTMS	Clinical Trials Monitoring System - electronic reporting method for reporting study toxicities - biweekly	http://www.theradex.com/ctms/ The CTMS is currently maintained by a non-Governmental organization (Theradex) contracted by NCI to receive, review and perform data management tasks on individual patient case report forms for Phase 1 investigational agent/intervention studies designated by NCI for such monitoring. Bi-weekly case report forms are submitted via CTMS. CTMS then uploads the data monthly to CDUS.
DCTD	Division of Cancer Treatment and Diagnosis - Division of the National Cancer Institute	http://dctd.cancer.gov/
DHHS	US Department of Health and Human Services	http://www.dhhs.gov
FDA	Food and Drug Administration - Regulatory agency within the US Department of	http://www.fda.gov

	Health and Human Services	
FDA Annual Report	Report on progress of clinical investigation	21 CFR 312.33 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.33
IDB	Investigational Drug Branch - A branch within CTEP responsible for evaluating Investigational agents of interest by the NCI	http://ctep.cancer.gov/branches/idb/default.htm
IDE	Investigational Device Exemptions	http://www.fda.gov/cdrh/devadvice/ide/index.shtml
IND	Investigational New Drug Application	http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm
InSight®	Regulatory Information Management and publishing software	https://www.liquent.com/technology/insight
Investigator Brochure	Brochure describing drug substance, formulation, preclinical studies and safety information of agent	21 CFR 312.23 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32

IPAD	Integrated Platform for Agents and Diseases	CTEP database application http://www.ctisinc.com/assets/files/publications/ipad.pdf (Please refer to an extended description of IPAD following the table of Definitions and Acronyms)
MedDRA	Medical Dictionary for Regulatory Activities	http://www.meddra.org/
MF	Master File	http://www.fda.gov/cder/guidance/dmf.htm
NCI	National Cancer Institute - Institute dedicated to cancer research within the National Institutes of Health	http://www.cancer.gov/
OA	Office of Acquisition - An office of the National Cancer Institute responsible for awarding and administering contracts.	http://ncioa.cancer.gov/oa-internet/index.jsp
OBA	Office of Biotechnology Activities	http://www4.od.nih.gov/oba/
RAB	Regulatory Affairs Branch - A branch within CTEP responsible for	http://ctep.cancer.gov/branches/rab/

	the preparation, management and submission of Investigational New Drug Applications (INDs) to the Food and Drug Administration and the coordination of all agreements with pharmaceutical collaborators.	
RABITS	Regulatory Affairs Branch IND Tracking System	An internal CTEP Enterprise database that tracks and supports IND submissions and CTEP Agreements (Please refer to an extended description of RABITS following the table of Definitions and Acronyms)
Rosetta Phoenix™	Rosetta Phoenix eCTD Viewer	http://www.rosettaectd.com/Rosetta/phoenix/eCTD_viewer.html
SPEER	Specific Protocol Exceptions to Expedited Reporting	http://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/aeguidelines.pdf#search=%22speer%22

The IPAD and RABITS are non-public facing applications and are components of the CTEP Enterprise system (CTEP-ESYS). Contractors will be provided access various levels of access to IPAD and RABITS via individual secure CTEP-ESYS passwords. If necessary, IPAD and RABITS training for the successor awardee will be conducted during Phase-out and Phase-in.

The CTEP-ESYS is a highly integrated enterprise system consisting of 26 applications. Some applications are available to clinical trial staff designed to facilitate data submission as required by federal regulation while the majority of the applications are accessible only by NCI/NIH personnel (and approved contractors) to assist in achieving the scientific goals of CTEP and the NCI while bringing operating efficiencies to new and future business practices.

The CTEP-ESYS contains records on all CTEP active and legacy trials, Investigational New Drug Applications (INDs), investigator registration, patient accruals and adverse events. The count of records is approximately:

INDs	125 (includes single and agent combinations)
Protocols	600 active trials
Accrual	30,000 patients annually
Investigator Registration Records	20,000
Associate Registration Records	38,000
Clinical Trial Sites	8,000

Historically, the CTEP-ESYS has been used by a community that included CTEP as well as other programs within DCTD such as the Cancer Imaging Program (CIP) and the Radiation Research Program (RRP), as well as Cooperative Group/NCTN and Cancer Center site staff and the Division of Cancer Prevention (DCP).

Integrated Platform for Agents and Diseases (IPAD)

The Integrated Platform for Agents and Diseases (IPAD) is a comprehensive web-based search tool that enables users to query and analyze structured and unstructured data across NCI CTEP enterprise applications and various external biomedical information resources. The tool also facilitates protocol performance monitoring and exploration of information related to clinical trial development and management.

- Production: 10/2010
- Users: CTEP Staff + Collaborators (Contractors)
- Functionality:
  - Keyword search and drill-down functionality
  - Graphical display of data
  - Standard reports
  - Saved searches and user preferences

Regulatory Affairs Branch Information Tracking System (RABITS)

The Regulatory Affairs Branch Information Tracking System (RABITS) facilitates the preparation and submission of INDs and associated IND amendments to the FDA. RABITS also improves the tracking of research agreements such as Clinical Trials Agreements (CTAs) and Cooperative Research and Development Agreements (CRADAs) for the co-development of investigational anticancer agents with industry collaborators.

- Production: 9/2005
- Users: Contractors, RAB, PMB (Non-CTEP INDs)
- Functionality:
  - Agreements Management

- IND Details Management
- IND Submission
- eSubmission Tracking